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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,008	03/02/2004	Huey Quoc Chan	1001.1765101	1275.

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EXAMINER

SMITH, PAUL B

ART UNIT PAPER NUMBER

3763

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/791,008	<b>Applicant(s)</b> CHAN ET AL.	
	<b>Examiner</b> Paul B. Smith	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/9, 7/2, 7/12.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 6/9/2004, 7/2/2004, and 7/12/2004 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner considers the references cited therein.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 12-15, 17-19, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Samson *et al.* ('978).

4. Samson *et al.* discloses a catheter comprising an elongated shaft (232), a working lumen (not referenced), an inflatable balloon (312), and an external inflation component (302). (See Figure 1-7) The inflation component comprises a reinforced braided polymer tube wherein the braid is composed of nitinol. The inflation component is a sleeve that is disposed around the elongate shaft. (See Column 10 Line 2) The inflatable balloon comprises silicone. (See Column 14 Lines 30-35) The elongated shaft comprises an internal braid of metal coils. (See Figure 3)

5. Thus, Samson *et al.* appears to reasonably teach every element of claims 1-7, 12-15, 17-19 and 25.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 8, 10-11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson *et al.* ('978) in view of Killion *et al.* ('957).

9. Samson *et al.* discloses a catheter comprising an elongated shaft (232), a working lumen (not referenced), an inflatable balloon (312), and an external inflation component (302). (See Figure 1-7) The inflation component comprises a reinforced

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braided polymer tube wherein the braid is composed of nitinol. The inflation component is a sleeve that is disposed around the elongate shaft. (See Column 10 Line 2) The inflatable balloon comprises silicone. (See Column 14 Lines 30-35) The elongated shaft comprises an internal braid of metal coils. (See Figure 3)

10. Samson *et al.* fails to disclose an inflation lumen that has a smaller diameter than the diameter of the shaft. Further, a means of attaching the inflatable balloon to the shaft is not specified.

11. Killion *et al.* teaches a balloon catheter comprising an inflation lumen that has a smaller diameter than the diameter of the elongated shaft. (See Figure 1) A means of attaching the inflatable balloon to the catheter is taught to be an adhesive or by thermal bonds. (See Column 4 Lines 5-15)

12. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Samson *et al.* with the teachings of Killion *et al.* to provide a balloon catheter with a smaller inflation lumen diameter than the shaft diameter. Further a means of attaching the balloon to the shaft is taught by Killion *et al.*

13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samson *et al.* ('978) in view of Pfenninger ('247).

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14. Samson *et al.* discloses a catheter comprising an elongated shaft (232), a working lumen (not referenced), an inflatable balloon (312), and an external inflation component (302). (See Figure 1-7) The inflation component comprises a reinforced braided polymer tube wherein the braid is composed of nitinol. The inflation component is a sleeve that is disposed around the elongate shaft. (See Column 10 Line 2) The inflatable balloon comprises silicone. (See Column 14 Lines 30-35) The elongated shaft comprises an internal braid of metal coils. (See Figure 3)

15. Samson *et al.* fails to disclose shrinking a thin wall of polymer around the inflation component and shaft.

16. Pfenninger teaches a method of bonding two lumens together comprising the steps of providing the lumens with a filling and surrounding them with a fitting shrinkable tubing. When the shrinkable tubing is selected appropriately, the supply of heat is just enough to shrink it so the two shaft areas are pressed together in shrinkage of the heat shrink tubing and are welded together at the same time. (See Column 7 Lines 10-20)

17. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Samson *et al.* with the teachings of Pfenninger to provide a means of attaching the inflation component to the shaft by shrinking a thin wall of polymer around the two.

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18. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samson *et al.* ('978) in view of Adams *et al.* ('292).

19. Samson *et al.* discloses a catheter comprising an elongated shaft (232), a working lumen (not referenced), an inflatable balloon (312), and an external inflation component (302). (See Figure 1-7) The inflation component comprises a reinforced braided polymer tube wherein the braid is composed of nitinol. The inflation component is a sleeve that is disposed around the elongate shaft. (See Column 10 Line 2) The inflatable balloon comprises silicone. (See Column 14 Lines 30-35) The elongated shaft comprises an internal braid of metal coils. (See Figure 3)

20. Samson *et al.* fails to disclose a sealing member that is a valve.

21. Adams *et al.* teaches a hemostatic valve at the proximal end of a inflation lumen. (See Column 5 Lines 25-30).

22. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Samson *et al.* with the teachings of Adams *et al.* to provide a sealing member that is a valve.

23. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson *et al.* ('978)

24. Samson *et al.* discloses a catheter comprising an elongated shaft (232), a working lumen (not referenced), an inflatable balloon (312), and an external inflation component (302). (See Figure 1-7) The inflation component comprises a reinforced braided polymer tube wherein the braid is composed of nitinol. The inflation component is a sleeve that is disposed around the elongate shaft. (See Column 10 Line 2) The inflatable balloon comprises silicone. (See Column 14 Lines 30-35) The elongated shaft comprises an internal braid of metal coils. (See Figure 3)

25. Samson fails to specifically disclose an inflation lumen with a diameter of about 0.002 inches at the distal end of the sleeve and 0.004 inches at the proximal end of the sleeve.

26. It would have been obvious to one of ordinary skill in the art to modify as claimed as a mere design choice lacking any criticality of size as being merely preferable for inflating the inflatable balloon depending on the ability of inflation fluid to transverse the lumen where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art.



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27. Claims 22-23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samson *et al.* ('978) in view of Eidenschink ('515).

28. Samson *et al.* discloses a catheter comprising an elongated shaft (232), a working lumen (not referenced), an inflatable balloon (312), and an external inflation component (302). (See Figure 1-7) The inflation component comprises a reinforced braided polymer tube wherein the braid is composed of nitinol. The inflation component is a sleeve that is disposed around the elongate shaft. (See Column 10 Line 2) The inflatable balloon comprises silicone. (See Column 14 Lines 30-35) The elongated shaft comprises an internal braid of metal coils. (See Figure 3)

29. Samson *et al.* fails to disclose a sleeve comprising a tapered distal end and a working lumen that tapers towards the distal end.

30. Eidenschink teaches a balloon catheter that comprises a sleeve distal end that is tapered and a distal lumen end that is tapered. (See Figuer 3)

31. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Samson *et al.* with the teachings of Eidenschink to provide a balloon catheter with a tapered distal end.

**Conclusion**

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. U.S. Patent 6,960,186 to Fukaya *et al.*
- b. U.S. Patent 6,905,477 to McDonnell *et al.*

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

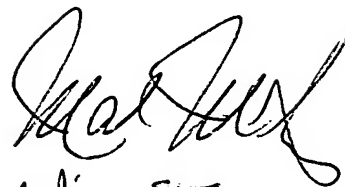
Paul B Smith

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Examiner  
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PBS  
July 6, 2006

A handwritten signature in black ink, appearing to read "Mark J. Hux". The signature is fluid and cursive, with the first name "Mark" being more legible than the last name "Hux".

Acting SPE  
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